July 27, 2011

Mr. Donald A. Heller
Corrective Action Section 1
Remediation and Reuse Branch
U.S. EPA, Region 5
77 W. Jackson Boulevard (LU-9J)
Chicago, Illinois 60604-3590

Re: Draft - Response to Comments
Revised Corrective Measures Study Report
Eli Lilly and Company – Evonik Degussa Corporation
Tippecanoe Laboratories
Lafayette, Indiana
IND 006 0500967

Dear Mr. Heller:

Eli Lilly and Company (Lilly) has prepared this letter to provide a preliminary response to comments provided in the comment letter issued by the U.S. Environmental Protection Agency (EPA) on July 1, 2011 on the on the above-referenced topic. After completing the conference call scheduled for August 2, 2011, Lilly will revise and re-issue this letter.

In preparation for the August 2, 2011 conference call, Lilly wanted to highlight two main points for focus during the call:

- Lilly agrees to move forward with performance of bench-scale testing to confirm that the identified treatment chemicals (i.e., RegenOx™ and ORC-Advanced®) will adequately address the constituent of concern (COC) concentrations. Based on the results of the bench-scale testing, Lilly will prepare and issue a Technical Memorandum to U.S. EPA that will transmit the results, conclusions, and recommendations. Prior to proceeding with implementation of the bench-scale testing, Lilly intends to develop and submit to U.S. EPA a bench-scale testing work plan for review and approval. Upon receiving approval, Lilly will move forward with implementation of the bench-scale testing, and based on the results of the bench-scale testing will either recommend performance of pilot-scale testing or design and implementation of a full scale remedial program.

  The preferred remedial alternative presented in the Revised CMS Report included targeted in-situ treatment of three areas and, after completion of the targeted in-situ treatment program, monitored natural attenuation (MNA). U.S. EPA's comment suggest that the Revised CMS proposed MNA as a stand-alone alternative. After completing the bench scale testing (and any associated recommendations associated with the results of the testing), Lilly will work with U.S. EPA to develop an efficient and effective MNA program.

Lilly envisions incorporation of the bench-scale testing (and any associated recommendations associated with the results of the testing) and an outline of the proposed MNA program into a Revised CMS Report. After receiving approval of the Revised CMS Report, Lilly will develop a Corrective Measure Implementation (CMI) program that will be used to guide implementation of the approved remedial alternative.

Lilly appreciates your continued input in implementation of an effective and efficient remedial approach at Tippecanoe Laboratories. If you have any questions or comments on the provided information, please contact me at (317) 276-8989.

Sincerely,

Philip L. Shinn, P.E.
Corrective Action Project Manager

cc: Doug Griffin – IDEM

Attachments: Attachment 1 – Response to Comments

ATTACHMENT 1
RESPONSE TO COMMENTS
JULY 1, 2011 U.S. EPA LETTER
REVISED CORRECTIVE MEASURES STUDY REPORT

Presented below are responses to specific comments included within U.S. EPAs July 1, 2011 comment letter.

Comment 1
(Page 2): EPA will not approve final corrective measures which include *in-situ* treatment without empirical data (i.e., bench and pilot testing with the impacted groundwater) which support the proposed additives' ability to eliminate the contaminants.

Response: Lilly understands that EPA intends to review empirical data on the effectiveness of the proposed in-situ treatment additives prior to final approval of corrective measures. Lilly believed that the Revised CMS Report provided information to support in-situ treatment as an effective remedial measure. The purpose of the Corrective Measures Study, is to identify and evaluate potential remedial alternatives for the releases that have been identified at the facility. OSWER Directive 9902.3-2A (May 1994). As part of this process, the respondent is required identify and screen potentially applicable technologies, develop the technologies that pass the screening process, complete the evaluation of the technologies, and identify the most appropriate technology for implementation. The Corrective Measures Implementation (CMI) Program is to design, construct, operate, maintain and monitor the performance of the corrective measure(s) selected by the implementing agency. OSWER Directive 9902.3-2A (May 1994). As part of the CMI,

U.S. EPA may require the respondent to conduct additional studies in order to support the CMI program. These activities would be performed during the design process and may include sampling and analysis and/or treatability studies.

Included within the Revised CMS Report, Lilly performed and/or proposed performance of the following activities to ensure that the Preferred Remedial Alternative would be appropriate for implementation:

- As part of the MNA study included in the Revised CMS Report, field and analytical laboratory data was gathered and utilized to assess if natural attenuation was occurring. This information was also used to confirm that the targeted in-situ treatment program would be effective (both from an oxidation and enhanced biodegradation perspective).

- Site geology, groundwater quality, and COC concentration and distribution data were provided to Regenesis (provider of RegenOx™ and ORC-Advanced®) to confirm that site conditions and the COCs could be effectively treated. Regenesis reviewed the information and confirmed that a combined treatment approach (RegenOx and ORC Advanced) would be effective in treating the COCs; however, prior to implementation of any ISCO/enhanced bioremedation process, bench-scale and pilot-scale studies should be conducted to select the appropriate treatment chemicals, quantity, and duration of injection.

- Preliminary bench-scale testing was performed to obtain a better understanding of the existing COC and groundwater properties (Section 4.3 and Appendix L). Conclusions and recommendations were developed from this testing, which included a recommendation for the performance of additional bench-scale testing prior to implementation of targeted in-situ chemical oxidation (ISCO)/enhanced bioremediation program. However, the results indicated that the recommended remedial approach was feasible.

- Section 6 of the Revised CMS report states:

  "Although a field pilot-scale test is the most meaningful indicator of RegenOx™ and ORC-Advanced® treatment feasibility, a bench-scale test is recommended to demonstrate the feasibility of these products to oxidize a specific contaminant under specific field conditions. The bench-scale test also provides a suitable method for calculating first-order degradation rates of both the contaminant and the treatment additive. The kinetic rates obtained in the laboratory should be considered as a prediction of degradation rates; however, it is likely that the bench-scale test will overestimate both the contaminant and treatment additive degradation rates. Therefore, after completing the bench-scale test, a pilot-scale test will be performed to further confirm that the approach will be effective."

> "Based on the results of the bench-scale and pilot-scale tests, it is important to understand that the conceptual design presented herein may be subject to revision. This revision may include the number of injection wells/points, injected chemical, injection events, and injected chemical quantity. In addition, the treatment program may be altered as groundwater monitoring data is gathered during implementation of the treatment program."

As presented in the Revised CMS Report, a preliminary bench-scale test was performed that confirmed that the remedial approach was feasible, the vendor that specializes in the performance of this remedial approach confirmed that the approach was feasible, and bench- and pilot-scale testing was recommended as part of the CMI program. In addition, a contingency plan was included as part of the remedial program evaluation process (Section 6.5), which stated that "If the evaluation confirms that a modification to the original program is required, Lilly would provide a technical memorandum to IDEM for review and approval where additional treatment deviates from the original approved plan."

Lilly believes that the information presented in the Revised CMS Report is sufficient to justify remedy selection. However, Lilly has agreed to move forward with performance of bench-scale testing to confirm that the identified treatment chemicals (i.e., RegenOx™ and ORC-Advanced®) will adequately address the COC concentrations. Lilly will submit to U.S. EPA a bench-scale testing work plan for review and approval. Upon receiving approval, Lilly will move forward with implementation. Based on the results of the bench-scale testing, Lilly will prepare and submit a Technical Memorandum to U.S. EPA that will transmit the results, conclusions, and recommendations. If a pilot test is necessary, Lilly requests that it be incorporated into the CMI Program.

Comment 2 (Page 2): Before EPA will continue its review of the CMS, Lilly must evaluate the efficacy of chemical additives for in-situ treatment with the contaminated groundwater at the Tippecanoe Laboratories and propose to EPA those additives which appear to be most effective, with empirical data to support the conclusion.

Response: See Response to Comment 1.

Comment 3 (Page 2): Such evaluation will also take into account possible mobilization of metals (particularly arsenic) from the soil when oxidizing or reducing conditions are induced.

Response: As presented in the Revised CMS Report, Lilly proposed to develop bench- and pilot-scale testing work plan(s) as the first step of the CMI Program. However, Lilly has agreed to move forward with performance of the bench-scale testing to confirm that the identified treatment chemicals will adequately address COC concentrations.

Lilly will develop and submit a bench-scale testing work plan to U.S. EPA for approval that will include an evaluation of the possible mobilization of metals from soil during implementation of the recommended remedial approach. Based on the results of the bench-scale testing, Lilly will either recommend performance of pilot-scale testing or recommend moving forward with updating the Revised CMS Report to obtain U.S. EPA approval to implement the full-scale program. Details regarding implementation of the remedial program will be included in the CMI Program, which will be submitted for agency approval.

Comment 4 (Page 2): Review of constituents of concern (COC) concentrations plotted over time in Appendix K of the CMS clearly indicate that levels of COCs are rising in numerous monitoring wells since the main plant recovery wells were shut down in 2005. Increases of COC concentrations are especially apparent over the most recent four to six quarters in many of the wells (i.e., T1809, T1814, T1815, T1816MW, T1830, T1874, and T1892).

EPA notes that the first line of evidence which supports monitored natural attenuation (MNA) as a component of the remedy requires historical groundwater monitoring data show a clear and meaningful trend of decreasing contaminant mass and/or concentration over time at appropriate monitoring locations (1998 OSWER Directive 9200.4-17P). Increasing COC concentrations and concentration vs. time plots which show no clear trend are not appropriate evidence as support for MNA as a remedy.

Response: U.S. EPA's analysis appears to be selective with regard to the quantity of wells reviewed and the time period analyzed. Furthermore, the term "many" is not accurate as U.S. EPA has only identified seven wells that were deemed to have COC concentration increases to be especially apparent, and U.S. EPA did not identify which COC concentrations in the identified wells were increasing. In addition, the method that U.S. EPA utilized to identify wells and assess the COC concentration trends was not provided.

A review of information included in the Revised CMS Report (Section 4.1, Appendix K, Executive Summary, and Section 5.6) demonstrated the following:

T1809 (n,n-DEA), T1814 (benzene and n,n-DEA), and T1815 (benzene) - COC concentrations were identified with an increasing trend as part of the Mann-Kendall analysis over the evaluation period. To address this issue, Lilly included this well within the footprint of the in-situ treatment program area.

T1892 (chlorobenzene and n,n-DEA) – This well was identified with increasing trends as part of the Mann-Kendall analysis over the evaluation period. This well is located hydraulically down-gradient of the Main Plant remedial response treatment area and should receive a benefit from the in-situ treatment program.

T1816MW, T1830, and T1874 - None of the COCs were identified in the Revised CMS Report with an increasing trend as part of the Mann-Kendall analysis over the evaluation period. U.S. EPA should provide information to identify which of the COCs they believe exhibit an increase concentration trend. After receiving this information, we can address U.S. EPAs concern.

Comment 5 (Page 2):

Lilly has noted that COC concentrations are decreasing at various monitoring locations throughout the plume. However, COC concentrations are increasing at key locations, specifically:

1 – Edge of the Wabash River bluff: T1815 (benzene, chlorobenzene, DEA), T1816 (chlorobenzene), T1816MW (chlorobenzene), and T1892 (DEA).

2 – Near center of mass of plume: T1809 (benzene, DEA, THF), T1814 (benzene and DEA), T1815 (benzene, chlorobenzene, DEA), T1818 (DEA), T1819 (DEA), and T1880 (DEA).

3 – Floodplain: T1874 (chlorobenzene) and T1875 (chlorobenzene).

4 – Southwest: T1855 (pCBT).

Response: 1 – Edge of the Wabash River bluff:

T1815 – This well is located near the central portion of the plume in the Main Plant, is not located at the edge of the Wabash River bluff, and a response is provided under Number 2 below.

T1816 (chlorobenzene) – This well was identified in the Revised CMS Report with an increasing trend as part of the Mann-Kendall analysis over the evaluation period. This well is located hydraulically down-gradient of the Main Plant remedial response treatment area and should receive a benefit from the in-situ treatment program.

T1816MW (chlorobenzene) – A discussion regarding the chlorobenzene concentration trend is provided in the response to Comment 4.

T1892 (DEA) – A discussion regarding the n,n-DEA concentration trend is provided in the response to Comment 4.

2 – Near center of mass of plume:

T1809 (benzene, DEA, THF) – A discussion regarding the n,n-DEA trend is provided in the response to Comment 4. Benzene and THF were not identified in the Revised CMS Report with an increasing trend as part of the Mann-Kendall analysis over the evaluation period.

T1814 (benzene and DEA) – A discussion regarding the benzene and n,n-DEA concentration trends is provided in the response to Comment 4.

T1815 (benzene, chlorobenzene, DEA) – A discussion regarding the benzene concentration trend is provided in the response to Comment 4. Chlorobenzene and n,n-DEA were not identified with an increasing trend in the Revised CMS Report as part of the Mann-Kendall analysis over the evaluation period.

T1818 (DEA) – This well was identified in the Revised CMS Report with an increasing trend as part of the Mann-Kendall analysis over the evaluation period. To address this issue, Lilly included this well within the footprint of the treatment area.

T1819 (DEA) – This well was identified in the Revised CMS Report with an increasing trend as part of the Mann-Kendall analysis over the evaluation period. This well is located immediately adjacent to the remedial response treatment area and is anticipated to receive benefit from the in-situ treatment program.

T1880 (DEA) – This well was identified in the Revised CMS Report with an increasing trend as part of the Mann-Kendall analysis over the evaluation period. To address this issue, Lilly included this well within the footprint of the treatment area.

3 – Floodplain:

T1874 (chlorobenzene) – This well was identified in the Revised CMS Report with a stable trend as part of the Mann-Kendall analysis over the evaluation period.

T1875 (chlorobenzene) – This well was identified in the Revised CMS Report with a stable trend as part of the Mann-Kendall analysis over the evaluation period. This well should receive benefit from the in-situ treatment program proposed in the vicinity of monitor well T1831.

4 – Southwest:

T1855 (pCBT) – This well was identified in the Revised CMS Report with an increasing trend as part of the Mann-Kendall analysis over the evaluation period. To address this issue, Lilly included this well within the footprint of the treatment area.

Comment 6 (Page 3): Figure 22 of the CMS depicts contaminant mass removal over time by the slurry wall/seepage collection system at the foot of the bluff. As evidence for plume stability Lilly notes that the rate of mass removal has decreased since approximately 2001, and Lilly states that it will continue to operate the seepage collection system primarily to prevent flooding of the Towpath Road. However, since 2005 (the year in which all recovery wells were shut down) the rate of contaminant mass removal has increased, which may indicate a corresponding increase in contaminant mass which is migrating downward and toward the Wabash River.

Response: Review of Figure 22 of the Revised CMS Report must be used in conjunction with the data provided in Appendix E, where a tabular summary of flow rates, COC concentrations, and mass recovered is presented. The slurry wall/seepage collection system includes sampling points T1465 and T1466; however, since minimal to no mass is recovered from T1466, the extraction volume and mass from this location was not included in the presentation. Provided below is a summary of the mass removal rates for T1465 (as presented in the CMS) and an additional summary that presents the mass removal rates for T1465 and T1466 combined:

T1465 Only:

2005	138.49 lbs / 4,614,280 gallons =	0.000030 lbs/gallon
2006	52.03 lbs / 3,787,981 gallons =	0.000014 lbs/gallon
2007	87.49 lbs / 6,313,056 gallons =	0.000014 lbs/gallon
2008	427.76 lbs / 13,531,667 gallons =	0.000032 lbs/gallon
2009	794.38 lbs / 12,608,168 gallons =	0.000063 lbs/gallon
2010	364.11 lbs / 11,531,984 gallons =	0.000032 lbs/gallon

Review of analytical laboratory data for 2007, 2008, 2009, and 2010 is presented below, which shows relatively consistent concentrations of COCs over time, with the exception of n,n-DEA:

	Average Concentration (ug/L)			
Constituent	**2007**	**2008**	**2009**	**2010**
THF	0.00	0.00	0.00	0.00
n,n-DEA	481	1,189	2,449	1,195
Benzene	2.67	4.17	4.46	3.78
Chlorobenzene	66	66	59	59
pCBT	3.91	3.47	4.11	0.00

Based on the above summary, the rate of mass recovery decreased from 2005 through 2007, returned to a rate relatively consistent with 2005 in 2008, increased in 2009, and in 2010 returned to a rate relatively consistent with the 2005 rate. However, the total quantity of mass has increased, which is due to the increased water recovery rate and an increase in n,n-DEA concentration.

Comment 7 (Page 3): From the evidence presented by Lilly to date and for the reasons described above, EPA believes that MNA is not an appropriate remedy. Lilly must evaluate the effectiveness of in-situ treatment technologies, determine time travel between contaminant source areas and sentinel and POC wells, and use predictive calculations to determine the threshold concentrations for the sentinel wells that warn when end point criteria will be exceeded at the POC wells. A method for calculating threshold concentrations at sentinel wells is explained in the comments which follow.

Response: The preferred remedial alternative presented in the Revised CMS Report included targeted in-situ treatment of three areas and MNA after completion of the targeted in-situ treatment program (See the Executive Summary and Section 6.0).

Lilly has agreed to move forward with performance of bench-scale testing to confirm that the identified treatment chemicals (i.e., RegenOx™ and ORC-Advanced®) will adequately address the COC concentrations. Based on the results of the bench-scale testing, Lilly will prepare and submit a Technical Memorandum to U.S. EPA that will transmit the results, conclusions, and recommends.

Lilly envisions incorporation of the bench-scale testing (and any associated recommendations associated with the results of the testing) and an outline of the proposed MNA program into a Revised CMS Report. After receiving approval of the Revised CMS Report, Lilly will develop a CMI Program that will be used to guide implementation of the approved remedial alternative. As part of the CMI Program, Lilly intends to implement a MNA program, after completing the targeted in-situ treatment program, to assess the effectiveness of the in-situ treatment program, estimate the time travel between contaminant source areas and sentinel and POC wells, and use predictive calculations to determine the threshold concentrations for the sentinel wells that warn when end point criteria will be exceeded at the POC wells. Making such calculations prior to conducting the proposed in-situ treatment would be a wasted effort since COC fate and transport processes will be significantly impacted by the proposed in-situ treatment program.

Comment 8 (Page 3):

In Table 9, Lilly states that: *Increased concentrations of ferrous iron [Fe(II)] may indicate ferric iron [Fe(III)] is being used as an electron acceptor during anaerobic biodegradation. During this process, iron (III) is reduced to Iron (II). Therefore, iron (II) concentrations can be used as an indicator of anaerobic degradation. Overall, a positive correlation between benzene concentration and ferrous iron concentrations should be expected.* Lilly further states: *Overall a positive correlation between benzene concentration and Mn+2 concentration should be expected. Elevate concentrations may indicate anaerobic biodegradation using carbon dioxide as an electron acceptor. Overall, a positive correlation between benzene concentration and mehane concentration should be expected. Decreased sulfate concentrations in the anaerobic portion of the plume may indicate use of sulfate as an electron acceptor for anaerobic biodegraatoin. Overall, an inverse relationship between benzene concentration and sulfate concentration should be expected.*
Actually, the positive correlation should not be between the geochemical parameter and the concentration of benzene or COC, but between the geochemical parameter and extent of degradation of benzene or the COC.

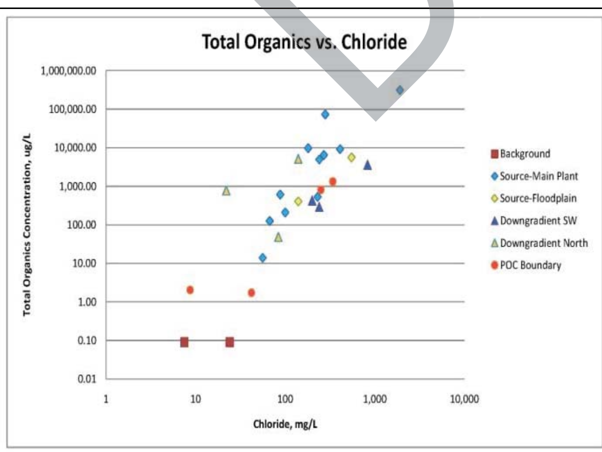
Response: The definition presented in the Revised CMS Report was presented in the MNA Study Work Plan and approved by U.S. EPA on June 17, 2009.

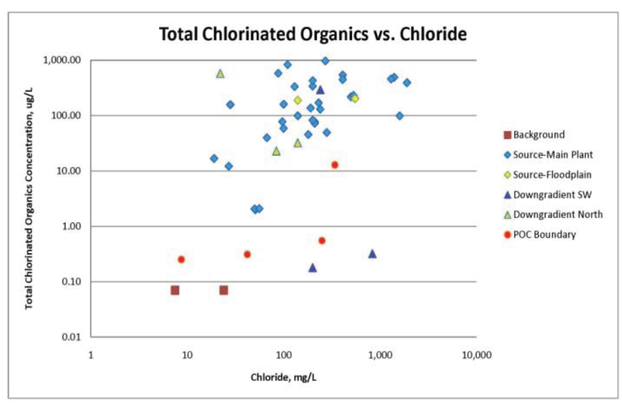
Additional Response Pending

Comment 9 (Page 4): On Page 83 Lilly states: *During biodegradation of chlorinated hydrocarbons dissolved into groundwater, chloride is released into the groundwater. This results in elevated chloride concentrations relative to background concentrations. The above graph provides a positive correlation between total organics and chloride concentration, which indicates that biodegradation of chlorinated hydrocarbons is occurring throughout the COC plume.*

As discussed above, the positive correlation should not be between the concentration of chloride and the concentration of total COC, but between the concentration of chloride and the extent of degradation of chlorinated VOCs. It is not clear why Lilly included n,n-diethylaniline as a COC in this comparison because it does not contain chlorine. In any case, the positive correlation does not indicate that biodegradation of chlorinated hydrocarbons is occurring throughout the COC plume.

Response: Lilly agrees that n,n-DEA and benzene do not contain chlorine; therefore, a revised figure has been prepared with only chlorinated compounds included. This figure depicts increased chloride concentrations in areas where higher concentrations of chlorinated COCs are present. This data does provide evidence that chlorinated COCs are undergoing biodegradation.





Original Figure 27 **Revised Figure 27**

Total Organics Concentration vs. Chloride Concentration

Comment 10 (Page 4):

However, if there is not a source of chloride in the process streams that were released into the groundwater, a comparison of the concentration of chloride to the concentration of organic chloride could be used as a rough index of the extent of biodegradation of the chlorinated organic compounds that were originally released. Figure 27 would be more useful if it compared organic chlorine in chlorobenzene and p-chlorobenzotrifluoride on a molar basis to the concentration of chloride in water on a molar basis.

Response:

There is not an independent source of chloride in the process streams released at the facility; therefore, Lilly believes that the provided comparison is appropriate to use as an indicator of biodegradation and a comparison that depicts chloride concentration compared to organic chlorine in chlorobenzene and pCBT on a molar basis is not necessary to reach a conclusion that biodegradation of chlorinated COCs is occurring. Lilly will evaluate if this analysis would provide benefit during future MNA events, after completing the targeted in-situ treatment program.

Comment 11 (Page 4):

On Page 85 Lilly states: *Since the measured ORP are all negative, with the exception of monitor well T1837, the groundwater is under reducing conditions, and anaerobic biodegradation is occurring throughout the COC plume.* Since the ORP values are all negative, that simply means that anaerobic degradation is possible, not that it is occurring.

Response:

Lilly agrees that the negative ORP values provide evidence that conditions are present to support anaerobic degradation.

Comment 12 (Page 4):

An inverse relationship between total organics concentration and dissolved oxygen concentration can be used as a key indicator of bioremediation. This is true; however, Figure 30 shows a direct relationship between total organics and oxygen, not an inverse relationship. As total organics go up, oxygen concentrations go up. Lilly further states: *As the above graph shows, dissolved oxygen concentrations are above 0.5 mg/L, indicating that anaerobic biodegradation is likely not occurring.* This is a contradiction to Lilly's statement on Page 85 that anaerobic biodegradation is occurring throughout the plume. Lily attempts to explain this with the following observation: *However, it is possible that the groundwater samples were somewhat aerated during purging and sampling, which would mask anaerobic conditions.* As will be discussed later, the groundwater is obviously not in geochemical equilibrium. Lilly reports high concentration of both oxygen and iron (II) in the same groundwater.

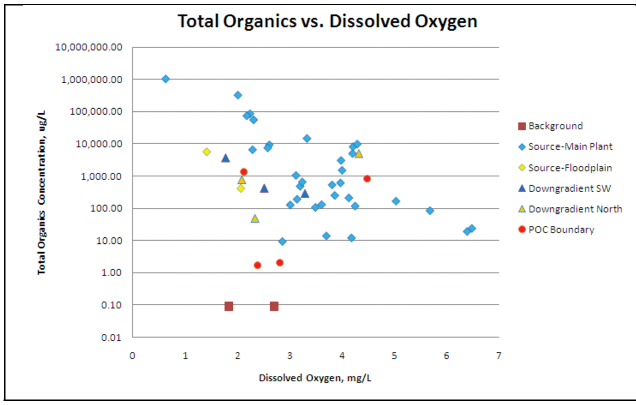
Response: Correct, Figure 30 shows a direct relationship between total organics and oxygen. Lilly also stated that DO concentrations were above 0.5 mg/L, indicating that anaerobic biodegradation is likely not occurring. This statement was an observation as a stand-alone data point not a conclusion for the entire COC plume. Lilly also noted that we believed that it was possible that the groundwater may have been aerated during purging and sampling, affecting the oxygen concentrations. As noted in U.S. EPA Comment 18, "The concentrations of dissolved iron and ferrous iron should be the same. If they are different, it is because the groundwater samples came into contact with oxygen at some time before they were filtered to determine dissolved iron."

In addition, U.S. EPA stated in Comment 25 that "As Lilly speculated earlier, the data on oxygen concentrations are probably spurious, and should not be interpreted here or anywhere else in the Draft Study. "

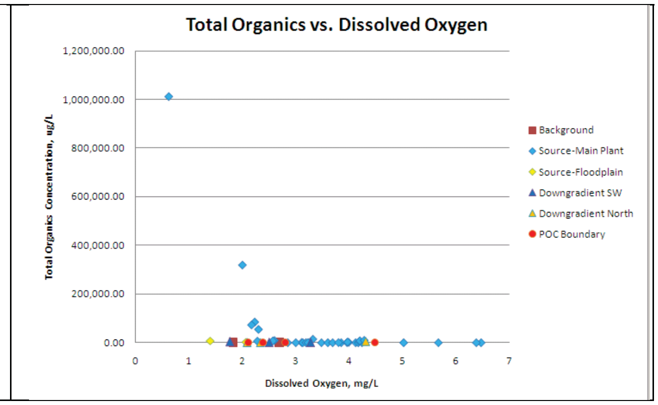
Comment 13 (Page 5): On Page 87 Lilly states*: At dissolved oxygen concentrations less than 4.0 mg/L, there is an inverse relationship between total organics concentration and dissolved oxygen, indicating that aerobic biodegradation is occurring. However, at higher dissolved oxygen concentrations, this inverse relationship is not observed. Many of the wells with higher dissolved oxygen concentrations also have increased concentrations of n,n-DEA, indicating that efficient biodegradation of n,n-DEA may not be occurring under aerobic conditions.*

In Figure 30, Lilly plots oxygen on a linear scale and total organic on a logarithmic scale. Their lowest reported concentration of oxygen is near 1.0 mg/L. To substantially affect this concentration of oxygen would require near 3,000 ug/L of benzene, which is near the top of the y-axis. If Figure 30 is used to make comparisons, both axes should be on a linear scale, and the total organics should be plotted as their oxygen demand, not their concentration. If Lilly is going to make a claim about oxygen and n,n-DEA, they should plot oxygen and n,n-DEA.

Response: Lilly used a semi-logarithmic scale for visualization purposes to identify a relationship (based on the wide range of concentrations). Figure 30 is presented below as shown in the Revised CMS Report (semi-logarithmic) and revised as requested by U.S. EPA (linear). As the figures demonstrate, all detail is lost for the lower total organics concentrations, minimizing the usefulness of the figure.



Original Figure 30



Revised Figure 30

Total Organics Concentration vs. Dissolved Oxygen

Also please note that Lilly did not draw any conclusions based on a semi-logarithmic straight line or conduct any regression analysis on these figures. In the Revised CMS Report, a "positive correlation" is defined as "the y-axis values appear to increase as the x-axis values increase" and an "inverse correlation" is defined as "the y-axis values appear to decrease as the x-axis values increase". Given the limited geochemical parameter dataset, Lilly believes that more rigorous statistical analysis of the geochemical parameters is neither justified nor necessary at this time.

Comment 14 (Page 5): This error is repeated in Figure 32 on Page 88, plotting the logarithm of total organics against the concentration of ammonia in water.

Response: Same response as Comment 13.

Comment 15 (Page 5): *The above graph shows a positive correlation between total organics concentration and ammonia, which indicates that nitrate is being reduced by microorganisms throughout the COC plumes.* Nitrate reduction usually, but not always, proceeds to make N2, not ammonia. Anaerobic degradation of n,n-DEA might produce ammonia.

Response: **Response Pending**

Comment 16 (Page 5): On Page 89 in Figure 33, the error is repeated of plotting the concentrations of total organics on a logarithmic scale.

Response: Same response as Comment 13.

Comment 17
(Page 5): On Page 90 Lilly discusses total iron. In groundwater at the pH of the plumes, dissolved iron is ferrous iron. The concentrations of dissolved iron and ferrous iron should be the same. If they are different, it is because the groundwater samples came into contact with oxygen at some time before they were filtered to determine dissolved iron. The oxygen converted the ferrous iron into ferric iron, which then precipitated and was removed on the filter.

Response: This comment supports the statement on Page 85 of the Revised CMS Report that stated that "*However, it is possible that the groundwater samples were somewhat aerated during purging and sampling, which would mask anaerobic conditions.*"

Comment 18
(Page 5): On Page 91, in reference to Figure 35, Lilly states: *The above graph shows no positive correlation between total organics concentration and manganese concentration. Therefore, manganese concentrations provide no evidence that anaerobic biodegradation is occurring within the COC plume.*

Figure 35 continues the error of plotting the logarithm of the total organics against the linear concentration of the geochemical parameter. No correlation would be expected. The absence of a linear correlation means nothing.

Response: Same response as Comment 13.

Comment 19
(Page 6): On Page 93, in reference to Figure 37, Lilly states: *The above graph shows a positive correlation between total organics concentration and carbon dioxide, which indicates that biodegradation is occurring within most of the COC plume.* Figure 37 continues the error of plotting the logarithm of the total organics against the linear concentration of the geochemical parameter.

Response: Same response as Comment 13.

Comment 20
(Page 6): On page 94, in reference to Figure 38, Lilly states: *The above graph shows a positive correlation between total organics concentration and methane, which indicates that methane is being produced and anaerobic biodegradation is occurring throughout the COC plume.* Figure 38 continues the error of plotting the logarithm of the total organics against the linear concentration of the geochemical parameter.

Response: Same response as Comment 13.

Comment 21 (Page 6): On Page 96, in reference to Figure 40, Lilly states: *Increased concentrations of organic carbon (as an electron donor) in the aquifer can support reductive dechlorination. The above graph indicates that there is an adequate supply of electron donor present within the groundwater plume to support reductive dechlorination.* Figure 40 continues the error of plotting the logarithm of the total organics against the linear concentration of the geochemical parameter. Further, there is a conceptual error. NRMRL created this rule of thumb in an effort to use total organic carbon as a surrogate for the native organic matter in groundwater that could support reductive dechlorination. Usually, the concentrations of total organic carbon are much higher than the concentration of carbon in the COCs. In this case the concentrations of COCs are so high they likely dominate the total carbon, and the rule should not be applied.

Response: Same response as Comment 13.

Additional Response Pending

Comment 22 (Page 6): On Page 97 Lilly states: *The results presented in the above summary table provide clear evidence that biodegradaation is occurring throughout the COC plume.* This is true; however, the results do not present clear evidence that the individual COC compounds are being degraded. Direct evidence for biodegradation of the four specific COC compounds for this facility is not presented in the Revised Corrective Measures Study Report.

Response: U.S. EPA's response confirms that biodegradation is occurring throughout the COC plume. Lilly does not agree with the U.S. EPA comment that the results do not present clear evidence that the individual COC compounds are being degraded and that there is no direct evidence for biodegradation of specific COCs in the Revised CMS Report. The specific COCs discussed in the Revised CMS Report represent the vast majority of dissolved contaminant mass at Tippecanoe. Therefore, there are no other COCs with sufficient mass to act as a substrate source. Lilly did consider performance of a detailed analysis for each of the primary COCs, but instead decided upon inclusion of Section 4.2.3.2, a more general discussion of the evidence of degradation for each of the five primary COCs. In addition, the trend analysis and the plume stability section (Section 4.1) of the Revised CMS Report present clear evidence that biodegradation of the main COCs is occurring.

Comment 23
(Page 6): Advances made since the release of OSWER Directive and Protocol for MNA of Chlorinated Solvents make it possible to recognize the degradation of a specific organic compound by changes in the ratio of stable isotopes remaining in the groundwater after degradation. This approach is described in A Guide for Assessing Biodegradation and Source Identification of Organic Ground Water Contaminants using Compound Specific Isotope Analysis (CSIA). D. Hunkeler, R.U. Mechenstock, B. Sherwood Lollar, T.C. Schmidt, J.T. Wilson. EPA 600/R-08-148 (December 2008) www.epa.gov/ada. This approach has been successfully applied to recognize and characterize the extent of degradation of benzene and chlorobenzene under anaerobic conditions in groundwater. See references in Hunkeler et al. (2008) and Isotopic Fractionatoin Indicates Anaerobic Monochlorobenzene Degradation, A. Kaschl, C. Vogt, S. Uhlig, I. Hijenhuis, H. Weiss, M. Kastner, and H.H. Richnow. Environmental Toxicology and Chemistry, Vol. 24, No. 6, pp. 1315-1324, 2005.

Response: Since MNA is not being proposed as a stand-alone remedial approach, but has been proposed to be implemented after completing targeted in-situ treatment program, Lilly believes that such analysis is neither justified nor necessary at this time. However, Lilly will evaluate if this analysis would provide benefit during future MNA events, after completing the targeted in-situ treatment program.

Comment 24
(Page 7): On page 99 in Table 12, Lilly compares concentrations of Iron (II) and dissolved oxygen. Both are very high. This is a geochemical impossibility. As Lilly speculated earlier, the data on oxygen concentrations are probably spurious, and should not be interpreted here or anywhere else in the Draft Study. This comment applies as well to tables 13, 14, 15, and 16.

Response: This comment supports the statement on Page 85 of the CMS Report that stated that "*However, it is possible that the groundwater samples were somewhat aerated during purging and sampling, which would mask anaerobic conditions.*"

Comment 25
(Page 7): Figure 41 would be more informative if the concentrations of benzene were plotted on a linear scale.

Response: Same response as Comment 13.

Comment 26 (Page 7):

On Page 101 Lilly notes: *The following graphs show a good positive correlation of chlorobenzene concentrations and chloride concentrations. This indicates that chlorbenzene is undergoing biodegradation. On this graph, it should be noted that wells located downgradient to the southwest have relatively high chloride concentrations, but non-detectable chlorobenzene concentrations. However, the pCBT plume extends to this area of the site, indicating that chloride is likely also being produced during the biodegradation of pCBT.*

This is a misunderstanding. The accumulation of chloride reflects the extent of degradation of chlorobenzene that has already occurred, not the amount of chlorobenzene available for biodegradation. One third of the total weight of chlorobenzene is organic chlorine. The figure would work better if the concentration of organic chlorine in chlorobenzene were plotted against concentration of chloride in solution using consistent units. When this is done, the data suggest that the amount of chlorobenzene that has been degraded is from one hundred fold to one thousand fold greater than the concentration of chlorobenzene currently present in the groundwater.

Response:

The intent of the text included in the Revised CMS Report is correct and confirms that the elevated chloride concentrations identified in the groundwater support the conclusion that biodegradation of chlorobenzene has occurred and is continuing to occur. In addition, U.S. EPA confirms in their response above that "the data suggest that the amount of chlorobenzene that has been degraded is from one hundred fold to one thousand fold greater than the concentration of chlorobenzene currently present in the groundwater." This statement confirms that a significant amount of natural attenuation has already occurred. Given current chlorobenzene concentrations and that groundwater conditions are not changing drastically, Lilly believes there is no reason or evidence to suspect that such natural attenuation would now cease to occur.

Comment 27 (Page 7):

Page 103. Most of the weight of pCBT is organic fluorine, and fluoride is rare in ambient groundwater. Lilly should try to track the pCBT plume using fluoride as a tracer, and compare the degradation of pCBT to accumulation of fluoride ion in groundwater. Fluoride may be a chemical of concern in groundwater.

Response:

Fluoride was not a stand-alone constituent utilized at the facility and has not been identified as a COC by U.S. EPA or IDEM. However, review of historic pCBT concentrations revealed a maximum concentration of 2,800 µg/L in a groundwater sample collected from monitor well T1816MW in September 2010. The pCBT concentration is less than 4,000 µg/L, which is the drinking water standard for fluoride. Therefore, there is no evidence that fluoride concentrations at the site, which would be expected to be less than the highest pCBT concentration, have ever exceeded the drinking water standard for fluoride.

Lilly will evaluate if this analysis would provide benefit during future MNA events, after completing the targeted in-situ treatment program.

Comment 28 (Page 7): Lilly makes the following statement: *However, in the vicinity of monitor wells T1811, T1892, and T1819, conditions remain aerobic. There are minimal VOC concentrations within these wells, which limits the amount of oxygen depletion and allows conditions to remain aerobic. Therefore, conditions are favorable for aerobic biodegradation of n,n-DEA within these areas of the plume. The n,n-DEA daughter product, aniline, was detected within the sample collected from monitor well T1811. Therefore, it appears that biodegradation of n,n-DEA is occurring within portions of the plume.* Considering the amount of Iron (II) in the water from these wells, it is very unlikely that oxygen is available for aerobic biodegradation of n,n-DEA.

Response: Lilly developed this text based on existing data, which revealed conditions that could support aerobic biodegradation of n,n-DEA. In addition, the presence of a daughter product (aniline) in monitor well T1811 provides further support that biodegradation has occurred.

Comment 29 (Page 9): The Revised Corrective Measures Study Report chooses to provide no information that can be used to estimate the second line of evidence, and presents no information to provide the third line of evidence, even though attenuation for two of the four COCs (pCBT and n,n-DEA) are by their own admission little understood.

Response: The MNA Study Work Plan, approved by U.S. EPA on June 17, 2009, included an evaluation of the first and second lines of evidence, but excluded an evaluation of the third line of evidence.

The second line of evidence, as presented in the comment letter, states: "Hydrogeologic and geochemical data that can be used to demonstrate indirectly the type(s) of natural attenuation processes active at the site, and the rate at which such processes will reduce contaminant concentrations to required levels." The Revised CMS Report presents geochemical data that clearly demonstrates that biodegradation is occurring throughout the COC plume (as confirmed in U.S. EPA comments), but does not present information on the rate of the processes. Lilly attempted to quantify degradation rates by methods presented by U.S. EPA and other documents; however, the current data set precluded estimation of degradation rates for individual COCs. Lilly intends to perform the degradation rate analysis after completion of the targeted in-situ treatment program and incorporate this analysis into the future MNA program.

Comment 30 (Page 9): Because the second and third lines of evidence are missing, the entire MNA proposal rests on the first line of evidence. Lilly proposes an evaluation path (Page 194) that is premature based on the information provided in the Revised CMS Report. They proposed to evaluate concentration trends using non-parametric statistics. If the concentration trends are stable or declining in more than 70% of wells Lilly proposes to take that as a line of evidence that the entire plume is stable.

Response: See response to Comment 29. In addition, Lilly believes that the approach presented on page 194 of the Revised CMS Report is reasonable but will work with U.S. EPA to refine the proposed evaluation process after completing the bench-scale testing (and any associated recommendations based on the results of the testing), Lilly will work with U.S. EPA to develop an efficient and effective MNA program.

Comment 31 (Page 10): Page 18 of OSWER Directive 9200-4-17P states explicitly: Therefore, sites where the contaminant plums are no longer increasing in extent, or are shrinking, would be the most appropriate candidates for MNA. It is EPA's intent that the term "stable" be defined as stable in space, as documented by the plume being confined within Point of Compliance wells.

"Stable" is not meant to be defined as a trend of decreasing concentration over time in monitoring wells. This is not EPA policy. There is no simple relationship between the volume of space occupied by a plume and the trend in concentrations. Many plumes have been shown to occupy more space over time while at the same time that concentrations at most of all monitoring wells have decreased.

In the OSWER Directive, the only reference to stable trends in concentrations is as follows: Typically, monitoring is continued for a specific period (e.g., one to three years) after remediation objectives have been achieved to ensure that concentration levels are stable and remain below target levels.

"Stable" as an interpretation of a statistical test for trends in concentration has no meaning for an evaluation of MNA. Stable in this sense simply means that the test could not detect either an increasing trend or a decreasing trend. The more variable the data, the more likely the trend will be "stable". Not being able to detect a trend is not the same as documenting that there is no increase in concentrations. "Stable" as an interpretation of the statistical test for trends in concentration simply means that one can't tell whether concentrations are increasing or decreasing. It does not mean the behavior of the plume is acceptable.

As required by the OSWER Directive for lines of evidence, the criterion should be that trends in concentration are decreasing, not "stable or decreasing". In addition, the criterion should be satisfied for each COC, and not for the aggregate of COCs. Based on the information provided above, the existing monitoring data fails to provide the first line of evidence of a decreasing trend in concentrations of the contaminants in even a simple majority of the wells, much less a preponderance of wells at the site.

Response: An analysis of plume stability was presented in Section 4.1 of the Revised CMS Report (including information presented Appendix K). This evaluation included six separate lines of evidence, in which one line of evidence was Mann-Kendall analysis (LOE 3). Therefore, Lilly's conclusion that the COC plumes are stable was not just based on "a trend of decreasing concentration over time in monitoring wells". Based on the lack of comments regarding plume stability, it does not appear that this portion of the Revised CMS Report was reviewed as part of the MNA review. Furthermore, the proposed approach on page 194 includes four LOEs (non-parametric statistical analysis, dissolved mass analysis, location of center of mass analysis, and plume footprint analysis), several of which address "stability in space". Again, Lilly will work with U.S. EPA to refine the proposed evaluation process on page 194, present the new process in the Revised CMS Report, and detail the MNA program/evaluation process in the CMI Program.

Comment 32 (Page 11): The summary of statistical analysis as reported in Appendix K, Section K.1.3 and summarized above does not mention the level of confidence in the statistical analysis. EPA should determine beforehand the level of confidence or acceptable level of error in the statistical comparisons. The acceptable level of error is the probability that the statistical test will report that concentrations are decreasing when in fact they are not decreasing. The level of confidence is one minus the level of error.

Response: Lilly will work with U.S. EPA to establish an appropriate level of error in the statistical comparisons. U.S. EPA's suggested level of confidence of 80% (see Comment 33) appears appropriate.

Comment 33 (Page 11): The confidence level in the evaluation of the trend should be 80% or higher. To allow for false negatives in the statistical comparisons at the 80% level of confidence, one might allow trends in the 20% of the wells to fail to show a decreasing trend, not 30% of the wells as suggested in the evaluation path on Page 194 of the Revised CMS Report.

Response: A level of confidence of 80%, equivalent to a level of error of 20%, appears reasonable. However, Lilly does not agree that only wells that show a decreasing trend support a demonstration of plume stability. If groundwater concentrations at a well are truly stable, for example a concentration of 50 µg/L is measured during every sampling event, then the groundwater system in the vicinity of that well is in equilibrium and therefore supports a conclusion that the plume is stable at that location. Lilly recognizes that the Mann-Kendall analysis tool used actually assigns a range of results to the "Stable/No Trend" outcome, some of which may actually be increasing or decreasing. Lilly will work with U.S. EPA to more specifically define the conclusions made from the results of the Mann-Kendall test, as well as to identify one which wells it is appropriate to perform Mann-Kendall analysis.

Comment 34 (Page 11): Further, to have a confidence in the efficacy of the MNA, the trends in concentrations in sentinel wells and in wells in the downgradient portions of the plume near the sentinel wells should be decreasing, not increasing or "stable". To have a confidence in the efficacy of MNA, the trends in the wells with higher concentrations of COCs should be declining.

Response: Lilly agrees that concentrations in monitor wells located down-gradient of a source area should not be increasing and that a decreasing trend in wells with higher concentrations of COCs provide confidence in the efficacy of MNA. In addition, Lilly believes that if a well is exhibiting a stable COC concentration trend, then any potential plume migration is in equilibrium with the rate of natural attenuation and this data would not support a conclusion that the plume is migrating.

Seasonal fluctuations can impact concentration trends within individual wells; therefore, Lilly believes that COC concentration trends in individual wells should be reviewed and considered; however, the stability of the COC plumes should be reviewed on a plume basis and not point by point.

Comment 35 (Page 11):

Regarding the sentinel wells, in order to calculate action levels for the COCs which when met or exceeded would indicate that End Point Criteria at the POC wells would be exceeded, Lilly should multiply the EPC for each COC by the discharge of the plume to the Wabash River (cubic meters of groundwater released to the river each minute) and then divide by the discharge of river at low stage (cubic meters of flow per minute). The Revised CMS Report does not provide enough data to estimate seepage velocity or Darcy velocity of groundwater in the plume. Therefore, the Revised CMS Report does not provide enough information to estimate the discharge of the plume to the river and does not make any estimate of the concentrations of the COCs that might impact the river.

Response:

This comment contradicts prior direction issued by U.S. EPA regarding this issue. Lilly completed this analysis of the Wabash River and included this information in the CMS Report issued to U.S. EPA in October 2007 (see Section 2.3.2). This analysis concluded that due to river dilution, the concentrations of COCs in the river would be approximately 250,000 times less than concentrations in groundwater. In other words, the discharge of the river is approximately 250,000 times the discharge of the plume to the Wabash River. This previous analysis can be provided if required.

In response to this evaluation, U.S. EPA required this information to be removed from the Revised CMS Report. However, Lilly agrees that this analysis is useful and demonstrates that the existing COC concentrations will not discharge to the Wabash River at concentrations that would create a negative impact to human health or the environment. Upon clarification from U.S. EPA, Lilly can re-submit this analysis as part of the CMS.

Comment 36 (Page 11):

Lilly proposes in-situ bioremediation through injection of chemical amendments into the contaminated aquifer. During this process, the extraction well pumps should be restarted. When in-situ bioremediation attempts to clean up an aquifer without circulating groundwater, it almost always fails to cleanup anything more than the region immediately around the well used to inject the amendments.

Response:

Lilly agrees. As presented in the Revised CMS Report (Executive Summary, Section 5.6.1.4, and Section 6.1); Lilly proposes placing recovery wells located within the area of treatment (T1809, T1814, and T1880) into service during performance of injection events to allow for distribution of treatment chemicals in the Main Plant treatment area.

Comment 37
(Page 12):

It is noted that the areas to be treated on the maps are approximately half the area between the wells with known contamination and wells without significant contamination. The site characterization has not delineated the true area of contamination, and there is no margin where contamination stops. This concern is illustrated by Figure 49 – T1831 Treatment Areas. How was it decided that a treatment area of 50 feet by 100 feet would cover all of the contamination?

Response:

The goal of the corrective measures in the Floodplain is to reduce contaminant mass in the source area to a degree such that it can be shown that POC EPC will not be reached in down-gradient POC wells. The targeted in-situ treatment program was not designed to "cover all of the contamination".